PHARMACIA

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 01D-0269; Draft Guidance for Industry on the Clinical Studies Section of Labeling for Prescription Drugs and Biologics-Content and Format (66 Federal Register 35797; July 9, 2001)

Dear Sir/Madam:

Pharmacia Corporation submits the following comments on the "Draft Guidance for Industry on the Clinical Studies Section of Labeling for Prescription Drugs and Biologics-Content and Format". Our comments are provided in accordance with the request as stated in the Federal Register (Vol. 66, No. 131 of July 9, 2001) to submit written comments by October 9, 2001. FDA subsequently extended the deadline by 45 days.

Pharmacia is in agreement with the comments sent to FDA by the Pharmaceutical Research and Manufacturers of America (PhRMA). We are providing the following comments on some issues of significant importance to Pharmacia.

- Pharmacia is concerned that this draft guidance unnecessarily focuses on the advertising and promotional implications of labeling for clinical studies. We believe that the proposed guidance should be revised to support and emphasize the primary goal of providing concise and accurate information that is most useful to prescribers in treating their patients. FDA has sufficient authority set forth in the Code of Federal Regulations to regulate advertising and promotion, as well as regulatory enforcement measures for breaches of such regulations.

- In subsection A3 of section III of the draft guidance, there is discussion of the types of endpoints that can be presented in the clinical studies section. We note the following statement: "When it would be informative, the CLINICAL STUDIES section can also discuss other endpoints that were shown to be affected by the drug and endpoints that would have been expected to be influenced by the drug but were

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not". What types of endpoints are referred to in this statement: pre-specified primary and secondary endpoints, others? This statement requires clarification and the types of endpoints should be defined. Description of the use of composite endpoints, primary and secondary endpoints, and closely related endpoints is somewhat vague. It would be helpful to clarify and expand the subsection on endpoints and provide some meaningful examples.

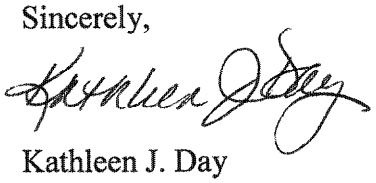
- Subsection E of section III contains a statement as follows: "Therefore, the CLINICAL STUDIES section should be carefully scrutinized to ensure that its content does not suggest or imply claims for indications, doses, regimens, or comparative effectiveness that are not adequately supported". This statement again overemphasizes advertising and promotional considerations. Furthermore, the information contained in this statement has been adequately presented in the proposed rule on content and format published in December 2000. It is also stated that "Words or phrases that lack a commonly understood meaning (e.g., imprecise quantitative terms), are not easily defined, are vague, are misleading, or are promotional in tone should be avoided". It should be pointed out that several of these words or phrases are frequently used and clearly understood by clinicians. Attempts to expand and further define these words or phrases may unnecessarily lengthen the label.

- Subsection F of section III refers to updating the CLINICAL STUDIES section when new, important information becomes available. This subsection is quite vague and provides no guidelines as to what FDA considers to be new, important information. This subsection needs further clarification and examples of new, important information should be provided.

Implementation guidelines are not set forth in the draft guidance. Thus, it is not clear whether the guidance is intended for existing drug labeling or new product labeling. It is Pharmacia's strong opinion that a final guidance should clearly state that the guidance applies only to new drugs or efficacy supplements.

We appreciate the opportunity to provide comments on the Clinical Studies Draft Guidance document and would be pleased to discuss these comments with the Agency at your request.

Sincerely,



Kathleen J. Day

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